REMARKS

Claims 1-9, 11-14, 20, and 23-40 are pending in the application before entry of this Amendment. Applicant appreciates the Examiner's allowance of claims 1-9, 11, 14, 20, 27-31, and 36-40. By way of this Amendment, claims 12 and 13 have been amended, and claims 41-46 have been added.

Rejection under 35 USC 112, 2nd Paragraph

Claims 12 and 13 are rejected as being indefinite. Specifically, the optional steps of "interconverting" and "deprotecting" are said to be vague and unclear. To clarify the claims, the interconverting step has been removed from claims 12 and 13 and rewritten in new dependent claims 41 and 42, respectively.

Thus, amended claims 12 and 13 provide for the reaction of reactant compounds R^1XH and $HNR^2(CR^5R^6)_nA$, respectively, with a compound of formula (III) to produce compounds of formula (I) and (IA), respectively, wherein the reactant compounds are optionally protected and the product compounds are optionally deprotected.

New claims 41 and 42 provide for the optional interconversion of the product compounds of formula (I) and (IA), respectively, into other compounds of formula (I) and (IA), respectively.

Support for the recited reactions (page 13-17), optional protection (page 18, ll. 6-13), and optional interconversion (page 17, ll. 18-27) is provided in the originally-filed specification. No new matter has been added.

Rejection under 35 USC 112, 1st Paragraph

Claims 23-26 and 32-35 are rejected under 35 USC 112, first paragraph as being non-enabled. Claims 23, 24, 32, and 33 are directed to methods of treating acute and chronic pain. Claims 25, 26, 34, and 35 are directed to methods of treating dysmenorrhoea.

Enablement of Acute Pain

Enablement for the method of treating acute pain is provided on page 7, line 31 and elsewhere in the originally-filed specification. The disclosed enablement is challenged by the Examiner as lacking evidence of working examples, level of skill in the art, and predictability.

The state of the art is demonstrated by FDA approved labels (Vioxx, 21-042, 5/20/1999, p.12; and Celebrex, 20-998, 7/29/2005, p.11) for previously or currently marketed Cox-2 inhibitors, submitted in an Information Disclosure Statement concurrently herewith. The labels demonstrate that the approved Cox-2 inhibitors were recognized as being efficacious for the treatment of acute pain. Thus, Cox-2 inhibitors were known to be useful for the treatment of acute pain.

Applicant asserts that the claimed compounds are enabled for the treatment of acute pain since the compounds have been shown to inhibit Cox-2, and since inhibition of Cox-2 was known in the art to be effective in treating acute pain.

Enablement of Chronic Pain

Enablement for the method of treating chronic pain is provided on page 7, line 31 and elsewhere in the originally-filed specification. The disclosed enablement is challenged by the Examiner as lacking evidence of working examples, level of skill in the art, and predictability.

The Examiner cites two references as representative of state of the art in Cox-2 inhibitors (Stichtenoth et al., Drugs, 63(1):33-45,2003, and Hochberg MC., Am. J. Manag. Care., 8(17Suppl):S502-517, 2002, full copy unavailable to Applicant). Stichtenoth summarizes (page 43) that "... Cox-2 inhibitors have proved to be fully efficacious in the therapy of pain and inflammation." Hochberg goes further by stating "The development of cyclooxygenase (COX)-2-selective inhibitors represents a major advance in the management of chronic pain and inflammation that may satisfy an unmet medical need...".

Thus, the references recognize the effectiveness of Cox-2 inhibitors in treating chronic pain. Applicant asserts that the claimed compounds are enabled for the treatment of chronic pain since the compounds have been shown to inhibit Cox-2, and since inhibition of Cox-2 is known in the art to be effective in treating chronic pain.

Enablement of Dysmenorrhoea

Enablement for the method of treating dysmenorrhoea is provided on page 7, line 31 and elsewhere in the originally-filed specification. The disclosed enablement is challenged by the Examiner as lacking evidence of working examples, level of skill in the art, and predictability.

The state of the art is demonstrated by FDA approved labels (Vioxx, 21-042, 5/20/1999, p.12; and Celebrex, 20-998, 7/29/2005, p.11) for previously or currently marketed Cox-2 inhibitors. The labels demonstrate that the approved Cox-2 inhibitors were recognized as being efficacious for the treatment of dysmenorrhoea. Thus, Cox-2 inhibitors were known to be useful for the treatment of dysmenorrhoea.

Applicant asserts that the claimed compounds are enabled for the treatment of dysmenorrhoea since the compounds have been shown to inhibit Cox-2, and since inhibition of Cox-2 was known in the art to be effective in treating dysmenorrhoea.

Added Claims for Neck and Back Pain

Claims 43-46 have been added. They are directed to a method of treatment of neck and lower back pain, and of non-specific lower back pain. Support for the amendment is provided on page 8, l. 2, 14-15 of the originally-filed specification.

Conclusion

Applicants respectfully submit that the instant application is in condition for allowance, which action is respectfully requested. The Examiner is invited to contact the undersigned at (919) 483-8160, to discuss this case, if desired.

Respectfully submitted,

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